ATTACHMENT B5 QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

Waste Isolation Pilot Plant Class 3 Permit Modification Request June 2005

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ATTACHMENT B5

QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

TABLE OF CONTENTS

B5-1 Quality Assurance Project Plans	B5-′
B5-2 Document Review, Approval, and Control	B5-

Waste Isolation Pilot Plant Class 3 Permit Modification Request June 2005

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QUALITY ASSURANCE PROJECT PLAN REQUIREMENTS

B5-1 Quality Assurance Project Plans

1

23

- 2 Prior to management, storage, or disposal of a generator/storage site's TRU mixed waste at
- WIPP, the Permittees shall require that each participating site develops and implements a
- quality assurance project plan (QAPjP) that addresses all the applicable requirements specified
- in Waste Isolation Pilot Plant waste analysis plan (WAP) in Permit Attachment B. The
- 6 Permittees will approve QAPiPs from all generator/storage sites that intend to send TRU mixed
- waste to the Waste Isolation Pilot Plant. The Permittees shall ensure that these QAPiPs include
- the qualitative or quantitative criteria for determining whether waste characterization analysis
- 9 program activities are being satisfactorily performed. The Permittees shall also ensure that
- QAPjPs identify the organization(s) and position(s) responsible for their implementation.
- Additionally, the QAPjPs shall also reference site-specific documentation that details how each
- of the required elements of the characterization waste analysis program will be performed.
- The Permittees shall ensure that prior to the implementation of characterization waste analysis
- activities at participating sites, standard operating procedures (SOPs) were developed for all
- activities which affect the quality of the waste characterization analysis program elements
- specified in the WAP. For the purposes of the quality assurance program, the term SOP refers
- to any site-specific implementing document. Compliance with SOPs will ensure that tasks are
- performed in a consistent manner that results in achieving the quality required for the quality
- assurance program. The organization, format, content, and designation of SOPs shall be
- described in the QAPjPs. Site-specific SOPs related to sampling and analysis will be reviewed
- for consistency with the QAPiP according to the Permittees' Audit and Surveillance Program
- specified in Permit Attachment B6.

B5-2 <u>Document Review, Approval, and Control</u>

- The Permittees shall ensure that the preparation, issuance, and change to documents that
- specify quality requirements or prescribe activities affecting quality for the transuranic mixed
- waste characterization analysis program activities specified in the WAP be controlled to assure
- that correct and current documents are used and referenced. The QAPiPs shall include a
- document control format consisting of a unique document identification number, current revision
- number, date, and page number which will be placed on the individual pages of the document.
- All quality documents for the waste characterization analysis program shall be reviewed prior to
- approval and issuance by qualified and independent individuals. The QAPiP review shall
- consider the technical adequacy, completeness, and correctness of the QAPjP, and the
- inclusion of and compliance with the requirements established by the WAP (Permit Attachment
- B). The Permittees shall ensure that appropriate QAPiP approval is indicated by a signature and
- date page included in the front of each document.
- At a minimum, the Permittees shall ensure that revisions to documents that implement the
- requirements of the WAP are denoted by including the current revision number on the document

- title page, the revised signature page, and each page that has been revised. Only revised pages need to be reissued. Changes to documents, other than those defined as editorial changes or minor changes, shall be reviewed and approved by the same functional organizations that performed the original review and approval, unless other organizations are specifically designated in accordance with approved procedures. Editorial or minor changes may be made without the same level of review and approval as the original or otherwise changed document. The following items are considered editorial or minor changes:
 - Correcting grammar or spelling (the meaning has not changed)
 - Renumbering sections or attachments
 - Updating organizational titles

- Changes to nonquality-affecting schedules
- Revised or reformatted forms, providing the original intent of the form has not been altered
- Attachments marked "Example," "Sample," or exhibits that are clearly intended to be representative only

A change in an organizational title accompanied by a change in the responsibilities is not considered an editorial change. Changes to the text shall be clearly indicated in the document. The Permittees shall provide the QAPjP for each site and all revisions to NMED upon approval by the Permittees.

The Permittees shall ensure that QAPjPs include a detailed description of the reporting and approval requirements for changes to approved QA documents and SOPs, including procedures for implementing changes to these documents. All members of the site project staff are responsible for reporting any obsolete or superseded information to the site project manager. All site-specific changes shall be evaluated and approved by the site project manager and the site project QA officer before implementation. The site project manager shall notify the appropriate personnel and the affected documents shall be revised as necessary. The site project manager shall also be responsible for notifying the DOE field office of the changes. The Permittees shall ensure that changes that affect performance criteria or data quality, such as sample handling and custody requirements, sampling and analytical procedures, quality assurance objectives, calibration requirements, or QC sample acceptance criteria comply with the WAP (Permit Attachment B) and shall not be made without prior approval of the Permittees. Prior to shipment of TRU mixed waste, the Permittees shall provide the approved QAPjP for each site, and all approved revisions, to the New Mexico Environment Department.